**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

**UNITED STATES OF AMERICA,**

**Plaintiff,**

**v.**

**UNDETERMINED QUANTITIES OF BOXES OF ARTICLES OF DEVICE, LABELED IN PART, SHELHIGH NO-REACT VASCUPATCH SHELHIGH, INC., undetermined quantities of boxes of articles of device, each box containing one jar, which contains the device labeled in part: SHELHIGH PULMONIC VALVE CONDUIT NO-REACT THREATED MODEL NR-4000 SHELHIGH, INC., (JAR), SHELHIGH NO-REACT PULMONIC VALVE CONDUIT SHELHIGH, INC., and all other quantities of all articles of device, with any lot number and in any size or type container that are labeled or unlabeled, including finished products, in-process materials, and raw materials used in the manufacture of such finished products, FUTURE MEDICAL DIAGNOSTICS MANUFACTURERS INC., 141 South Avenue, Suite 200-205, Fanwood, New Jersey,**

**Defendants.**

**MASTER FILE: 07-CV-1769 (WJM)**

**OPINION**

**HON. WILLIAM J. MARTINI**

Arnold Allan Gordus, Jr.
United States Department of Justice
1331 Pennsylvania Avenue NW
Suite 950 North
Washington, DC 20004

Peter W. Gaeta
Office of the U.S. Attorney
970 Broad Street
Suite 700

Newark, NJ 07102

Eric Michael Blumberg
United States Food & Drug Administration
5600 Fishers Lane
Room 6-13
Rockville, MD 20857

(*Counsels for Plaintiff*)

Marco A. Laracca
Bio & Laracca, P.C.
331 Central Avenue
Orange, NJ 07052

Paul A. Logan
Powell, Trachtman, Logan
1814 East Route 70
Suite 304
Cherry Hill, NJ 08003

(*Counsels for Defendant*)

**WILLIAM J. MARTINI, U.S.D.J.:**

Shelhigh has filed a motion for relief from a consent order that terminated this litigation. Shelhigh argues that this relief is justified because unexpected changes in the factual circumstances under which Shelhigh consented to the order make its continued enforcement inequitable. Shelhigh also requests an evidentiary hearing to establish the

facts constituting its alleged changed circumstances. This Court finds that even under the facts as Shelhigh alleges them, Shelhigh is not entitled to the relief it seeks. Accordingly, Shelhigh's request for a hearing and underlying motion are **DENIED**.

## I. FACTS AND PROCEEDINGS

This case centers around the federal government's seizure of illegally manufactured medical devices. Shelhigh, Inc., manufactures medical devices designed for implant into humans, including cardiovascular, neurological, and general surgery devices. (Compl. ¶ 8.) Shelhigh sells these devices to hospitals and surgeons throughout the world. (Mot. for Relief. at 2.) In 2007, the Federal Food and Drug Administration ("FDA") seized these devices, pursuant to a warrant from this Court. (Mot. at 2; Compl. ¶ 1.) The FDA alleged that the methods and facilities Shelhigh used in the manufacture, design, packing, storage, and installation of these devices made them unsuitable for domestic sales under the Federal Food, Drug and Cosmetic Act and regulations promulgated thereunder. (Mot. at 2; Compl. ¶ 6.) Specifically, the FDA's complaint alleged that the devices were "adulterated" as defined by 21 U.S.C. § 351(h) (2000) and were thus subject to seizure and condemnation. (Compl. ¶ 6.)

Shortly after the government seized the Shelhigh medical devices, Shelhigh filed a motion for an order to show cause why this Court shouldn't order the government to release these devices for export to Italy and Spain. (Mot. for Order to Show Cause at 1.) Shelhigh argued that even if its medical devices were adulterated under the Food, Drug

and Cosmetic Act's manufacturing standards for domestic sales, the devices were not adulterated under that Act's standards for exports. (Mot. for Order to Show Cause at 1–2.) As part of this argument, Shelhigh asserted that Italy and Spain had already determined that Shelhigh's devices complied with the relevant health and safety regulations in those countries.[1] (Mot. for Order to Show Cause at 8.) After issuing the Order to Show Cause, this Court denied Shelhigh's request for an order to release the seized items, reasoning that it could not determine whether the devices were adulterated under the Act's standards for exports without an evidentiary hearing. (Order Denying Prelim. Inj. at 2–5.)

During this period in litigation, Shelhigh made two general equitable arguments to this Court that the factual circumstances of this case mitigated against allowing the continued seizure of its medical devices. First, Shelhigh argued that the seizure of its goods was causing it severe and irreparable harm, including employee layoffs and possibly bankruptcy. (Decl. of Gabbay, Economic Harm to Shelhigh.) Second, Shelhigh argued that the seizure of its devices would prevent many hospital patients worldwide from receiving needed medical care, noting that its devices were the sole medical hope for many patients. (Decl. of Gabbay, Patients Need Shelhigh.)

Despite these gloomy predictions, Shelhigh eventually entered into a consent order

---

[1]Compliance with the health and safety standards of the importing country is required before the Food, Drug and Cosmetic Act allows a manufacturer to export devices that it could not distribute domestically. 21 U.S.C. § 381(e)(1)(B).

with the FDA that settled this litigation. The consent order generally provides terms under which the FDA will release certain seized devices to Shelhigh for certain purposes. Also of note in the consent order, Shelhigh CEO Dr. Shlomo Gabbay and his wife, Lea Gabbay, appeared as defendants and "voluntarily consented to the entry of [the] Order without contest." (Consent Order at 2.) The consent order purports to make all defendants, including Dr. Gabbay and Lea Gabbay, liable to the United States for the costs of supervising compliance (Consent Order ¶ 27), for liquidated damages in the event of noncompliance (Consent Order ¶ 31), and for several other types of potential financial damages.

Shelhigh now moves under Rule 60(b) and pursuant to this Court's inherent judicial authority for relief from this consent order.[2] Shelhigh seeks modification of the consent order to allow it to export medical devices to European countries that have agreed to import them. (Mot. at 1.) Shelhigh also seeks modification of the consent order to allow it to sell devices as unfinished component devices, which Shelhigh claims do not violate FDA regulations. (Mot. at 21.)

Shelhigh makes several arguments that its current factual circumstances justify

---

[2]At times, Shelhigh frames its request as a motion to show cause. (See Mot. at 1.) But a motion to show cause is usually a request for a preliminary injunction, L. R. Civ. P. 65.1, which is not the relief that Shelhigh seeks. Rather, this Court construes Shelhigh's motion simply as a motion for relief from judgment under Rule 60, see Marshall v. Weyerhaeuser Co., 456 F. Supp. 474, 478 n.2 (D.N.J. 1978), and this Court has granted Shelhigh an expedited briefing schedule and return date pursuant to Federal Rule of Civil Procedure 6.

such relief. First, Shelhigh argues that the consent order imposes upon Shelhigh an onerous financial burden that will eventually force Shelhigh out of business. (Mot. at 1.) Shelhigh claims that compliance with the consent order is impossible and that noncompliance will result in liquidated damages under the order and possibly bankruptcy. (Mot. at 14–16, 18.) Second, Shelhigh argues that since entry of the consent order, several more European countries have determined that the seized devices comply with their health and safety regulation. (Mot. at 1, 5–11.) Shelhigh accordingly requests modification of the consent order to allow for export to these countries. (Mot. at 1.) Third, Shelhigh argues that hospital patients worldwide need the seized medical devices and that the seizure will force those patients to use substitute devices that may result in a lower quality of patient life and higher mortality rates. (Mot. at 11.) Fourth, Shelhigh argues that it is now seeking to manufacture only unfinished medical devices, and Shelhigh claims that this use of its seized devices would be legal under the Food, Drug and Cosmetic Act. (Mot. at 19–20.)

The Government replies that Shelhigh's circumstances have not changed since entry of the consent order and that any changes have been small and expected. (Opp'n to Mot. at 8–16.) The Government also argues that Shelhigh legally cannot export its devices or sell them domestically as unfinished component parts. (Opp'n at 16–24.)

In Shelhigh's reply brief, Shelhigh raises new arguments to support its request for relief. Primarily, Shelhigh argues that the FDA has not complied with the terms of the

consent order. (Reply Br. at 3–13, 18.) Specifically, Shelhigh alleges that the FDA has failed to make good faith efforts to cooperate with Shelhigh in devising a plan to comply with the order. (Reply Br. at 3–13.) Shelhigh also argues that the consent order's imposition of liability upon Dr. Gabbay and Lea Gabbay is particularly harsh and deserving of relief.

## II. DISCUSSION

### A. Shelhigh's Request for an Evidentiary Hearing

Shelhigh has requested an evidentiary hearing to prove the material facts underlying its claim to relief (Mot. at 1), but this Court finds that an evidentiary hearing is not warranted. Shelhigh purportedly wishes to use such a hearing to establish its circumstances have changed since entry of the consent order. Specifically, Shelhigh seeks to establish that since entry of the consent order its financial status has worsened and that several more European countries have approved its devices for export. But the government does not challenge either of these types of material facts. The government only argues that both grounds are legally insufficient to justify relief from the consent order. As explained below, this Court agrees.[3] Accordingly, an evidentiary hearing is

[3]Shelhigh's request for an evidentiary hearing is generally quite vague, and it has been only through conversations with Shelhigh's counsel that this Court has been able to discern precisely what Shelhigh wishes to establish with a hearing. Given that Shelhigh makes only the most generalized request for a hearing and that Shelhigh's motion fails even on the facts as Shelhigh alleges them, this Court will not further speculatively analyze the merits of a hearing.

unnecessary.

**B. The Merits of Shelhigh's Rule 60(b) Motion**

The relief that Shelhigh requests—modification of or relief from an order to which Shelhigh voluntarily consented—is extraordinary and appropriate only in exceptional circumstances. This Court finds such circumstances absent here and accordingly denies Shelhigh's motion.

**1. Shelhigh's Alleged Changed Circumstances**

Shelhigh argues that relief from its consent order is warranted in light of changed circumstances. This Court disagrees.

A court's power to modify a consent order and its power to grant relief from that order stem from two different sources. As Shelhigh observes, district courts have inherent power to modify a consent decree in response to changed conditions. Holland v. N.J. Dep't of Corr., 246 F.3d 267, 270 (3d Cir. 2001). The power to grant relief from a consent decree, however, which includes the power to modify, also stems from Federal Rule of Civil Procedure 60(b) which allows a district court to relieve a party from a final judgment, such as a consent order. See Phila. Welfare Rights Org. v. Shapp, 602 F.2d 1114, 1119 (3d Cir. 1979). Shelhigh moves for relief under Rule 60(b)(5), which allows relief from a final judgment if "applying it prospectively is no longer equitable."[4]

[4]Shelhigh also moves for relief under Rule 60(b)(6), which allows relief from a final judgment for "any other reason that justifies relief," but that paragraph does not apply here. Rule 60(b)(6) is a catchall provision, appropriately used when no other Rule

Although this Court's power to modify a consent order and its power to grant relief from a consent order stem from two different sources, the standards for determining whether to exercise these powers in the face of changed circumstances are similar, if not identical. As mentioned above, the exercise of either power is an extraordinary remedy. Shapp, 602 F.2d at 1119; see Holland, 246 F.3d at 283.

Where the party seeking relief from or modification of the consent order is the defendant, their burden is even greater. They must show a "significant change . . . in factual conditions" that makes compliance with the consent order "substantially more onerous." Holland, 246 F.3d at 284 n.16 (quotation omitted). This change must be unanticipated by the defendant seeking modification. Id. The more rigorous standard for defendants seeking modification recognizes that defendants usually seek modification "not to achieve the purposes of the provisions of the decree, but to escape their impact." Id. (quoting United States v. United Shoe Mach. Corp., 391 U.S. 224, 249 (1968)).

Here, it doesn't appear that any of the circumstances that Shelhigh alleges to have changed since Shelhigh entered into the consent order have actually changed in any significant way. Shelhigh asserts that the consent order has left it in dire financial straits (Mot. at 1), increasing the likelihood of layoffs and bankruptcy, but Shelhigh also alleged this before it entered into the consent order (Decl. of Gabbay, Economic Harm to

---

60(b) provision is applicable. Here, however, Shelhigh's argument fits neatly within Rule 60(b)(5)'s jurisprudence, as this Opinion will shortly explain, and this Court sees no "other reason that justifies relief."

Shelhigh). Shelhigh asserts that since entry of the consent order, several European nations have approved its devices for export (Mot. at 1, 5–11), but even before entry of the consent order, Shelhigh argued that Italy and Spain had approved its devices for export (Mot. for Order to Show Cause at 1). Shelhigh asserts now that continued seizure of its devices deprives patients worldwide of needed medical care (Mot. at 11), but this too Shelhigh asserted before entry of the consent order (Decl. of Gabbay, Patients Need Shelhigh). Finally, Shelhigh asserts that it can legally sell its devices domestically as mere unfinished components (Mt. 19–20), but Shelhigh fails to argue that this was not true when Shelhigh entered the consent order. Thus, Shelhigh's circumstances have not changed substantially since entry of the consent order.

Furthermore, any changes were anticipated. With respect to Shelhigh's increasingly dire financial situation, Shelhigh knew when it entered the consent order that allowing the FDA to continue to seize its devices subject only to gradual release would be a financial burden. (Decl. of Gabbay, Economic Harm to Shelhigh.) Also, Shelhigh must have anticipated that after Italy and Spain approved its devices for import that other European nations might follow. With respect to the worldwide need for Shelhigh's medical devices an the legality of Shelhigh's proposal to sell unfinished medical products domestically, it does not appear that any meaningful changes have occurred since entry of the consent order, as discussed above.

Finally, Shelhigh argues that modification of the consent order to permit Shelhigh

to manufacture and sell unfinished medical devices would accomplish the FDA's goals. (Mot. 21.) Shelhigh reasons that following such a modification Shelhigh would no longer be manufacturing devices in violation of the Food, Drug and Cosmetic Act. (Mot. 21–22.)

But Shelhigh overstates this Court's discretion to consider the consent order's purpose when deciding whether to modify it. District courts may modify consent decrees to further their purpose "only upon making a finding that conditions have changed so that the 'basic purpose of the original consent decree' has been 'thwart[ed].'" Id. at 283 (alteration in original) (quoting Chrysler Corp. v. United States, 316 U.S. 556, 562 (1942)). Here, as noted above, conditions have changed little since the entry of the consent decree. Furthermore, it is not clear that the purpose of the consent order has in any way been "thwarted." If its purpose is simply to prevent Shelhigh from manufacturing and distributing medical devices in violation of the Food, Drug and Cosmetic Act, then that purpose appears to be fulfilled, whether Shelhigh survives or not.

More generally, this Court will not expend too much time determining whether the single "purpose" of the consent order has been thwarted in some theoretical way. A consent agreement may have many purposes, each of which may be furthered by different outcomes. As the Supreme Court has stated:

> [T]he [consent] decree itself cannot be said to have a purpose; rather the parties have purposes, generally opposed to each other, and the resultant decree embodies as much of those opposing purposes as the respective parties have the bargaining power and skill to achieve. For these reasons,

> the scope of a consent decree must be discerned within its four corners, and not by reference to what might satisfy the purposes of one of the parties to it.

United States v. Armour & Co., 402 U.S. 673, 681 (1971), *quoted in* Fox v. U.S. Dep't of Hous. and Urban Dev., 680 F.2d 315, 319 (3d Cir. 1982). This Court will not delve beyond the four corners of the parties' consent agreement in a search for its purpose.

**2. The FDA's Alleged Breach of the Consent Order**

In Shelhigh's reply brief, Shelhigh argues for the first time that relief from the consent order is warranted because the FDA has breached the consent order.[5] (Reply at 3–13, 18.) This Court will not consider issues first raised in a reply brief and rejects Shelhigh's argument solely on that basis. See Bayer AG v. Schein Pharm., 129 F. Supp. 2d 705, 716 (D.N.J. 2001).

It is worth noting, however, that this argument appears without merit for two reasons. First, Shelhigh has not made clear that the FDA has breached the consent order. The Third Circuit has reiterated numerous times that when interpreting and enforcing an unambiguous consent order, courts are bound by the "four corners" of that document.

---

[5]Shelhigh claims that its argument is permissible as a response to the government's statement that "[n]or is this a case in which the defendant seeks relief from a decree because the government has implemented the decree in an abusive manner [or] has interpreted the decree unreasonably." But the government's observation in its opposition that Shelhigh had not made this argument does not open the door for Shelhigh to subsequently present it for the first time in a reply brief. Such a "passing reference" is insufficient to raise the issue of the FDA's compliance with the consent order. See Bayer, 129 F. Supp. 2d at 716.

McDowell v. Phila. Hous. Auth., 423 F.3d 233, 238 (3d Cir. 2005); United States v. New Jersey, 194 F.3d 426, 430 (3d Cir. 1999); Max's Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros, 176 F.3d 669, 673 (3d Cir. 1999); Harris v. City of Philadelphia, 137 F.3d 209, 212 (3d Cir. 1998); Farley v. Phila. Hous. Auth., 102 F.3d 697, 700 (3d Cir. 1996).

Shelhigh, however, does not allege the FDA violated any specific provision in the consent order. Rather, Shelhigh argues the FDA violated "collateral agreements" it made with Dr. Gabbay. (Reply at 4.) For example, Shelhigh argues the FDA orally agreed not to advise the public to refrain from using Shelhigh products already in distribution. (Reply at 3.) This Court will not delve beyond the express obligations of the consent order to consider such"collateral agreements." Shelhigh also argues that the FDA "implemented the Consent Order in an abusive and unreasonable manner." (Reply at 8.) For example, Shelhigh alleges that the FDA failed to promptly respond to Shelhigh's proposals for implementing the consent order. (Reply at 8.) But again, Shelhigh fails to present violations of specific provisions in the consent order. The only provision of the consent order that Shelhigh references in this respect is a provision stating that "defendants shall consult with FDA before developing and submitting a reconditioning plan," which Shelhigh argues the FDA violated by requiring an in-person submission. (Reply at 8.) This picayune requirement hardly seems to breach the consent order.

Second, even assuming arguendo that the FDA breached the consent order, Rule 60(b) does not provide the proper remedy. Breach of a settlement agreement, even when

entered into the record as a consent order, does not normally constitute grounds to vacate or modify that agreement. See Sawka v. Healtheast, Inc., 989 F.2d 138, 140 (3d Cir. 1993) ("Assuming *arguendo* that Healtheast breached the terms of the settlement agreement, that is no reason to set the judgment of dismissal *aside*, although it may give rise to a cause of action to *enforce* the agreement."); Apple Corps Ltd. v. Int'l Collectors Society, 15 F. Supp. 2d 456, 470 (D.N.J. 1998). The most appropriate remedy for the breach of a consent order is for the rendering court to enforce that order. See Sawka, 989 F.2d at 141. To this end, the court may extend certain provisions of the consent order, but even this is justified only in the face of "pervasive violations" or "substantial non-compliance." Holland v. N.J. Dep't of Corr., 246 F.3d 267, 283–84 (3d Cir. 2001). This ensures that the parties receive the benefits and bear the burdens of their bargain.

Here, however, Shelhigh does not seek to enforce the agreement. Rather, it appears that Shelhigh seeks modification of the consent order "not to achieve the purposes of the provisions of the decree, but to escape their impact." Holland, 246 F.3d at 284 n.16 (quoting United Shoe, 391 U.S. at 249). But as explained above, Shelhigh does not present grounds for such relief. Shelhigh must fulfill the obligations to which it submitted.[6] If Shelhigh desires this Court's assistance in ensuring that the FDA fulfills the obligations to which it submitted, Shelhigh has remedies available to it.

---

[6]For this reason, Shelhigh presents no justification for relieving Dr. Gabbay and Lea Gabbay from liability. While this may present a hardship, this is the burden to which they have submitted.

## III. CONCLUSION

In conclusion, while Shelhigh appears to be in dire straits, its situation has changed little since the entry of the consent order, and it surely anticipated any changes. Accordingly, its motion for modification of or relief from the consent order is **DENIED**. An appropriate Order accompanies this Opinion.

s/ William J. Martini
William J. Martini, U.S.D.J.